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EXAMINER

WILSON, MICHAEL C

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,575

Applicant(s)

CANTRELL ET AL.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-58 and 66-87 have been canceled. Claims 59-65 remain pending and are under consideration in the instant office action.

Applicant's arguments filed 2-16-05 have been fully considered but they are not fully persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 – new matter

The rejection of claims 59-65 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn.

Specifically, the previous rejection has been withdrawn because the phrases "wherein the shell is deposited around a female pronucleus before the female pronucleus joins a male pronucleus" (claims 59, 64 and 65) and "the embryo develops from the joining of the female pronucleus and the male pronucleus in the shell" (claims 59, 64 and 65) have been deleted.

The phrase "native embryo" as newly amended is found in the paragraph bridging page 11-12.

Claim Rejections - 35 USC § 112 – indefiniteness

The rejections of claims 59-65 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention have been withdrawn in view of the amendments to claims 59, 64 and 65.

In the interview summary from 2-1-05, the examiner agreed that the paragraph bridging pg 11-12 of the specification supported the phrase "native embryo" as claimed but thought the phrase would require reinstating the indefiniteness rejection made 10-31-02 on pg 8. Applicants were reminded that to prevent reinstating the 112/2nd rejection applicants must adequately argue the specification as originally filed would have allowed one of skill to conclude that i) the phrase "native embryo" is limited to an embryo that develops and hatches in the same shell in which the female pronucleus used to make the embryo was formed and ii) the phrase "native embryo" excludes embryos that have been removed from their shells and put into new shells in which they later are born.

Claims 59, 64 and 65 as newly amended require a "native embryo." The rejection regarding the phrase "native embryo" made 10-31-02 is hereby reinstated.

The phrase "native embryo" is indefinite because it is a relative term, is not adequately defined in the specification and the claim does not state to what the embryo or yolk is native. The paragraph bridging pg 11-12 states:

"In another embodiment, the present invention provides an oviposited avian egg comprising a native embryo having fewer than 40,000 cells, wherein the embryo can develop into a live chick. "Native" means growing, living or produced in its place of origin. Thus a native embryo is an embryo that develops and hatches in the same shell in which the female pronucleus was formed. Thus, the embryo is descended from the native ovum. By the time an ovum which has been fertilized naturally has been oviposited, the developing embryo typically has between 40,000 and 70,000 cells. However, the egg of the present invention is fertilized after it has been oviposited in its shell, thus, an embryo developing in the egg of the present invention will at some time during incubation have fewer than 40,000

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cells. In fact, at the moment of activation, the embryo in the egg of the present invention will have one cell and is a zygote."

Thus, a "native embryo" encompasses an "embryo that develops and hatches in the same shell in which the female pronucleus was formed." However, the sentence is not the only one describing the concept of "native embryos" and does not limit the definition to "embryos that develop and hatches in the same shell in which the female pronucleus was formed." The sentence describing "native" must also be considered, which says, "native means growing, living or produced in its place of origin." Thus, it appears that the definition also includes an embryo that hatches from a transplant, recipient shell because it grows and lives in the shell and is hatched from the shell. The transplant, recipient shell may also be considered the embryo's "place of origin" because it is the place from which the bird hatches and is born from.

Applicants argue under written description that the phrase is limited to an embryo that develops and hatches in the same shell in which the female pronucleus used to make the embryo was formed (pg 6 of response filed 2-16-05) but does not provide any explanation or reasoning why the phrase as defined in the specification is limited to such embodiments or why the phrase excludes embryos that have been removed from their shells and put into new shells in which they later are born.

Upon review of this rejection, the examiner would consider withdrawal the rejection if applicants concede that the phrase was intended to be limited to "embryo that develops and hatches in the same shell in which the female pronucleus was formed" but has a broader meaning because of the way "native" is more broadly

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defined. Therefore, applicants must concede that the phrase "native embryo" encompasses 1) an embryo that develops and hatches in the same shell in which the female pronucleus was formed; 2) an embryo that has been removed from its shell and put into a new shell in which it later is born (Naito); 3) and a fertilized ovum transferred into the birth canal of a chicken, passed through the female reproductive system so that a shell forms, laid and hatched (Tanaka) and 4) an embryo that develops from an oviposited oocyte removed from its shell and put into culture medium (Johnston). If applicants do not concede that the phrase "native embryo" is broader than "an embryo that develops and hatches in the same shell in which the female pronucleus was formed", this indefinite rejection will be maintained.

Claim Rejections - 35 USC § 102

Claims 59-65 as newly amended are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449), of record in the office action of 10-31-02.

Tanaka taught an oviposited chicken egg comprising a fertilized ovum (pg 447, col. 2, "Materials and Methods"; pg 448, Fig. 1) made by transferring a day old fertilized ovum into the birth canal of the chicken. A shell formed around the fertilized ovum as it passed through the recipient hen's reproductive system, the egg was laid on the day following the transfer (pg 448, col. 1, line 4) and a chick hatched (pg 448, col. 2, first full ¶, line 9). The egg is oviposited as claimed because a shell forms around it and is

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passed through the birth canal. The day old fertilized ovum had less than 10,000 cells as claimed because a zygote is one cell. The embryo is a "native" as claimed because it grows, lives and hatches from the egg shell that forms around it in the female reproductive tract. The shell that forms around the fertilized ovum is easily considered the embryo's "place of origin" as used in description of "native embryos" in the sentence bridging pg 11-12 of the specification because the shell is the place in which the embryo grows, lives and hatches. A "native embryo" is not limited to an embryo that develops and hatches in the same shell in which the female pronucleus was formed as in the sentence bridging pg 11-12. The definition of "native" on pg 11, lines 27-29, is broader and encompasses any embryo growing, living or produced in its place of origin. The embryo of Tanaka is growing, living and hatches from a shell that forms around the embryo in the female reproductive tract; the shell that forms around the embryo in the female reproductive tract is the embryo's "place of origin." Thus, Tanaka meets all the limitations of the claims.

Claims 59-65 as newly amended are rejected under 35 U.S.C. 102(b) as being anticipated by Johnston (1998, Poultry Science, Vol. 77, pg 142), of record in the office action of 10-31-02.

Johnston taught an oviposited oocyte with a shell used for fertilization by injecting sperm onto the oocyte (line 9 and 6 lines from the bottom), which is equivalent to an oviposited chicken egg as claimed. The fertilized oocyte is equivalent to an embryo or zygote as claimed and is less than 10,000 cells as claimed because it is one cell that

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proliferates (last sentence). The fertilized oocyte is an "egg from which a live chick can hatch" because the fertilized oocyte proliferates (last sentence). Without evidence to the contrary the egg described can hatch. However, the limitation "from which a live chick can hatch" is an intended use and does not bear patentable weight under 102 because it may not occur. The limitation "from which a live chick can hatch" also does not distinguish the structure of the egg claimed from the structure of the egg described by Johnston.

The embryo proliferating in a culture system described by Johnston is a "native" embryo as claimed because it is growing in its place of origin. A "native embryo" is not limited to an embryo that develops and hatches in the same shell in which the female pronucleus was formed as in the sentence bridging pg 11-12. The definition of "native" on pg 11, lines 27-29, is broader and encompasses any embryo growing, living or produced in its place of origin. Any one of the three conditions meets applicants' definition of "native." The embryo of Johnston is "native" because it grows in a culture medium, which is "its place of origin" because fertilization took place in culture medium. Thus, Johnston meets all the limitations of the claims.

Claims 59-65 as newly amended are rejected under 35 U.S.C. 102(b) as being anticipated by Naito (1990, J. Exp. Zoo., Vol. 254, pg 322-326) as supported by Olsen (J. Morph., 1942, Vol. 70, pg 513-533, Ref DC in the IDS filed 9-4-01), both of record in the office action of 8-26-03.

Naito isolated a chicken embryo 2.5-2.75 hr after fertilization from the reproductive tract of a chicken. The embryo was transferred into an eggshell with a hole drilled in it, incubated and hatched (pg 323, col. 1, Systems I and II). The embryo is inherently a zygote (one cell) because it is less than 3 hours old (Olsen, pg 523, lines 1-3). The egg is an "oviposited egg" because the egg has "a calcium carbonate shell that has been extruded from the vagina of a bird" as defined in the specification. The embryo is "native" because it is in a shell from which it hatches, i.e. its "place of origin" (see the description of "native embryos" in the sentence bridging pg 11-12 of the specification). The embryo is "native" to the recipient shell because the shell is the place in which the embryo grows, lives and hatches. A "native embryo" is not limited to an embryo that develops and hatches in the same shell in which the female pronucleus was formed as in the sentence bridging pg 11-12. The definition of "native" on pg 11, lines 27-29, is broader and encompasses any embryo growing, living or produced in its place of origin. Thus, Naito meets all the limitations of the claims.

Claim Rejections - 35 USC § 103

Claims 59-65 as newly amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (1998, Poultry Science, Vol. 77, pg 142) in view of Goldberg (1992, Ped. Research, Vol. 32, pg 23-26), both of record.

Johnston injected sperm onto an oviposited oocyte that had been removed from its shell (line 9 and 6 lines from the bottom). The oviposited oocyte is equivalent to an oviposited chicken egg as claimed. The fertilized oocyte is equivalent to an embryo or

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zygote as claimed and is less than 10,000 cells as claimed because a fertilized oocyte has one cell that proliferates (last sentence). The fertilized oocyte is an "egg from which a live chick can hatch" because the fertilized oocyte proliferates (last sentence). The embryo proliferating in a culture system described by Johnston is a "native" embryo as claimed because it is growing in its place of origin. This meets the definition of "native" on pg 11, lines 27-29 (an embryo "growing, living or produced in its place of origin"). A "native embryo" is not limited to an embryo that develops and hatches in the same shell in which the female pronucleus was formed as in the sentence bridging pg 11-12. The embryo of Johnston is "native" because it grows in a culture medium, which is "its place of origin" because fertilization took place in culture medium. Johnston did not teach injecting the sperm onto the oocyte in the shell from which it came as described in the specification (or that the embryo developed from the joining of the female pronucleus and the male pronucleus inside a shell as previously claimed).

However, Goldberg taught injecting five solutions into eggs using a 1 mm window (¶ bridging pg 23-24).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject sperm onto an oviposited chicken oocyte as taught by Johnston through a 1 mm window in the shell as taught by Goldberg. This would have resulted in the joining of the male and female pronuclei in the shell. One of ordinary skill in the art at the time of the invention would have been motivated to inject sperm onto the oocyte while the oocyte was still in the shell using a 1 mm window to decrease the amount of change to the oocytes surroundings and to maintain the integrity of the egg.

Applicants argue the motivational statement is not found in the references (pg 9, 1st full ¶ of response). Applicants argue the motivational statement has no scientific basis (pg 11, 1st sentence of 2nd full ¶ of response). Applicants' arguments are not persuasive. The motivational statement need not be a direct quote from the references. The motivational statement is based on basic, non-scientific reasoning, i.e. injecting sperm through a hole in the shell would prevent the step of culturing the embryo in vitro and keep the embryo in its natural surroundings.

Applicants argue Johnston does not support an embryo from which a live chick can hatch as claimed. Applicants' argument is not persuasive. First, the limitation "from which a live chick can hatch" is an intended use and does not bear patentable weight under 102 because it may not occur. Second, the fertilized oocyte described by Johnston could be transferred to a shell and hatch because Johnston taught the fertilized oocyte proliferates (last sentence). Therefore, without evidence to the contrary the egg described by Johnston can hatch. Third, the combined teachings of Johnston and Goldberg produces an egg having the same structure described in the instant application. Therefore, an egg "from which a live chick can hatch" as claimed does not distinguish the structure of the egg claimed from the structure described by the combined teachings of Johnston and Goldberg.

Applicants argue Goldberg does not teach injecting sperm into eggs or discuss fertilizing oocytes. Therefore, applicants' conclude Goldberg does not cure the deficiencies of Johnston (pg 11, 1st full ¶, of response). Applicants' argument is not persuasive. Goldberg provided an advantage for injecting compounds into eggs, which

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is all that is required. The fact that Goldberg injected compounds onto a fertilized oocyte instead of an unfertilized oocyte as described by Johnston is irrelevant.

Goldberg represents the knowledge of those skilled in the art at the time of filing – that various compounds could be injected directly into an egg (fertilized or unfertilized) using a small window in the shell. One of ordinary skill would have recognized the technique of injecting compounds to an egg using a window was well known in the art and applied to any oocyte or egg (i.e. fertilized or unfertilized).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, one of ordinary skill in the art would have recognized that injecting an egg using a window as described by Goldberg provided the advantage of eliminating the need to remove the oocyte from the shell and culture it in vitro prior to injecting sperm for fertilization and the advantage of eliminating over-manipulating the oocyte.

Double Patenting

Claim 64 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 63. When two claims in an application are duplicates or else are so close in

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content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Perry of record (1988, Nature, Vol. 331 , pg 70-72). Perry taught a fertilized oocyte recovered from the magnum of a killed hen surrounded by a capsule of dense viscous albumen (pg 71, Fig. 1A caption). The specification states "reference to an avian egg in a shell refers to an oviposited egg, that is, an egg with a calcium carbonate shell that has been extruded from the vagina of the bird" (pg 7, lines 23-25). Perry does not apply as art because the fertilized oocyte isolated by Perry was not "oviposited" as claimed, i.e. not an egg with a calcium carbonate shell extruded from the vagina of the bird.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER